DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 0 6 2011

Immunodiagnostic Systems ltd.
c/o Mick Fenton
Regulator Affairs Officer
10 Didcot way
Bolden Business Park
Boldon, Tyne & Wear, NE35 9PD, UK

Re: k111650
Trade Name: IDS-iSYS CTX-I (Crosslaps®) Calibration Verifiers, IDS-iSYS 25 Hydroxy Vitamin D Calibration Verifiers, and IDS-iSyS CTX-I (Crosslaps®) Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: June 8, 2011
Received: June 13, 2011

Dear Mr. Fenton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

INDICATIONS FOR USE

K number **K111650**

Device **IDS-iSYS CTX-I (Crosslaps) Control Set**

The IDS-iSYS CTX-I (CrossLaps) Control Set is intended for medical purposes for use in the IDS-iSYS CTX-I (Crosslaps) Assay on the IDS-iSYS Multi-Discipline Automated Analyser to monitor the accuracy and quality of the IDS-iSYS CTX-I (Crosslaps) Assay.

Prescription Use __X__ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111650

INDICATIONS FOR USE

K number K111650

Device **IDS-iSYS 25-Hydroxy Vitamin D Calibration Verifiers**

The IDS-iSYS 25-Hydroxy Vitamin D Calibration Verifiers are intended for use in the quantitative verification of calibration and assay range of the IDS-iSYS 25-Hydroxy Vitamin D Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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510(k) K111650

INDICATIONS FOR USE

K number **K111650**

Device **IDS-iSYS CTX-I (Crosslaps) Calibration Verifiers**

The IDS-iSYS CTX-I (CrossLaps) Calibration Verifier is a device intended for medical purposes for use in the quantitative verification of calibration and assay range of the IDS-iSYS CTX-I (CrossLaps®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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